IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BRAINTREE LABORATORIES, INC.,

Plaintiff,

v. Civil Action No. _____

LANNETT COMPANY, INC.

Defendant.

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff, Braintree Laboratories, Inc. ("Braintree" or "Plaintiff"), sues Defendant, Lannett Company, Inc. ("Lannett"), and alleges:

NATURE OF THE ACTION

1. This is an action for infringement of U.S. Patent No. 6,946,149, as reexamined ("the '149 patent"), arising under the patent laws of the United States, Title 35, United States Code, 35 U.S.C. §§ 271 and 281. This action relates to Abbreviated New Drug Application ("ANDA") No. 209941, filed by Lannett with the U.S. Food and Drug Administration ("FDA") and seeking approval to market a generic version of Braintree's SUPREP® drug product.

PARTIES

2. Braintree is a corporation organized and existing under the laws of the Commonwealth of Massachusetts, with its principal place of business at 60 Columbian Street West, Braintree, Massachusetts 02185-0929.

3. Upon information and belief, Lannett is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 9000 State Road, Philadelphia, Pennsylvania 19136.

4. Upon information and belief, following any FDA approval of ANDA No. 209941, Lannett will make, use, offer to sell, and/or sell the generic products that are the subject of ANDA No. 209941 throughout the United States, and/or import such generic products into the United States.

JURISDICTION AND VENUE

5. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100, *et seq*, and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a). Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b).

6. Upon information and belief, this Court has personal jurisdiction over Lannett, under 10 Del. C. § 3104 and other applicable law, because, *inter alia*, Lannett has purposely availed itself of the rights and benefits of the laws of Delaware by engaging in persistent, systematic and continuous contacts with Delaware, such that it should reasonably anticipate being subject to suit here. In particular, Lannett is registered with the Delaware Department of State Division of Corporations as a Domestic Corporation, with a registered agent in Milford, Delaware.

7. Upon information and belief, Lannett regularly and continuously transacts business within the State of Delaware, including availing itself of the privilege of conducting business within Delaware by developing, manufacturing, marketing, and selling prescription and over-the-counter pharmaceutical products there for use by Delaware citizens. Upon information and belief, Lannett derives substantial revenue from its Delaware drug sales. For instance, Lannett holds two licenses with an Active status from the State of Delaware Division of

Professional Regulation, as a Pharmacy Wholesaler and also as a Controlled Substances Distributor/Manufacturer. *See* Delaware Division of Professional Regulation, *available at* https://dpronline.delaware.gov/mylicense%20weblookup/Search.aspx?facility=Y (enter Lannett).

8. Upon information and belief, Lannett will develop, manufacture, market, and/or sell within the United States the generic version of Braintree's SUPREP® drug product described in ANDA No. 209941 if FDA approval is granted. If ANDA No. 209941 is approved, the generic version of Braintree's SUPREP® charged with infringing the '149 patent, would, upon information and belief, be manufactured, marketed and distributed in Delaware, prescribed by physicians practicing in Delaware, dispensed by pharmacies located within Delaware, be listed as a reimbursed product in the Delaware Department of Health and Social Services Medicaid system, and/or used by persons in Delaware, all of which would have a substantial effect on Delaware.

9. Braintree enjoys sales in Delaware of its SUPREP® drug product, which is covered by the claims of the '149 patent. If the FDA approves ANDA No. 209941, Lannett's manufacturing, marketing and sales of its generic version of Braintree's SUPREP® will cause Braintree substantial injury in Delaware.

10. Upon information and belief, Lannett has previously availed itself of this forum for the purpose of litigating business disputes. In *Impax Laboratories, Inc. et al. v. Lannett Holdings, Inc. and Lannett Company, Inc.*, Case No. 1:14-cv-00999-RGA (D. Del.), Lannett waived any argument that it was not subject to personal jurisdiction in this District, pursuant to Federal Rules of Civil Procedure 12(b) and (h)(1)(B), by failing to move to dismiss for lack of personal jurisdiction, and admitted in its Answer that it was subject to personal jurisdiction in this District for that litigation (*id.*, ECF No. 11, ¶11). In *Lannett Company, Inc. v. KV Pharmaceuticals et al.*, Civ. No. 1:08-cv-00338-JJF (D. Del.), Lannett selected this District to

file suit against a Delaware corporation with its principal place of business in Missouri and its two subsidiaries, one a Delaware corporation and the other a Missouri corporation with a principal place of business in Missouri.

BACKGROUND

11. Braintree holds approved New Drug Application ("NDA") No. 22372 for SUPREP® Bowel Prep Kit ("SUPREP"). SUPREP is a sodium sulfate, potassium sulfate and magnesium sulfate osmotic laxative and was approved by the FDA on August 5, 2010. SUPREP is indicated for bowel cleansing prior to an adult patient having a colonoscopy procedure.

12. Pursuant to 21 U.S.C. § 355 (b)(i) and attendant FDA regulations, the '149 patent has been listed in connection with SUPREP in the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations,* which is referred to as the "Orange Book." SUPREP, or its use or formulation, is covered by one or more claims of the '149 patent.

THE '149 PATENT

13. Braintree is the lawful owner by assignment of the '149 patent, entitled "Salt Solution for Colon Cleansing," which was duly and legally issued by the U.S. Patent and Trademark Office on September 20, 2005. The '149 patent was the subject of an *ex parte* reexamination procedure that Braintree requested on October 15, 2008. A reexamination certificate was issued by the U.S. Patent and Trademark Office on June 30, 2009. As a result of the reexamination, it was determined that claims 1, 6, 8-9, 13-14, 17 and 21 were cancelled, claims 2-4, 7, 10, 15 and 18 were patentable as amended, and claims 5, 11-12, 16, 19-20 and 22-23, each dependent on an amended claim, were patentable. A true and correct copy of the '149 patent and its reexamination certificate are attached hereto as **Exhibit A**. The claims of the '149 patent are valid and enforceable.

14. The ’149 patent, *inter alia*, claims compositions and methods for use of the compositions for inducing purgation of the colon.

15. The ’149 patent will expire no earlier than March 7, 2023.

16. Braintree, as the owner of the entire right, title and interest in the ’149 patent, possesses the right to sue for infringement of the ’149 patent.

INFRINGEMENT BY LANNETT

17. By letter dated February 8, 2017 (“Lannett Notice Letter”), Lannett notified Braintree that Lannett had submitted ANDA No. 209941 to the FDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)), seeking approval, prior to the expiration of the ’149 patent, to engage in the commercial manufacture, use, or sale and/or importation of the sodium sulfate, potassium sulfate and magnesium sulfate oral lavage solution currently listed in the Orange Book for SUPREP.

18. By filing ANDA No. 209941, and upon information and belief, Lannett has represented to the FDA that the components of its proposed generic sodium sulfate, potassium sulfate and magnesium sulfate oral solution, respectively 17.5g/3.13g/1.6g per bottle, have the same active ingredients, the same route of administration, dosage form, and the same strengths as the corresponding components of SUPREP. By filing ANDA No. 209941, and upon information and belief, Lannett necessarily represented that its proposed generic sodium sulfate, potassium sulfate and magnesium sulfate oral solution is bioequivalent to SUPREP.

19. Lannett has committed an act of infringement, pursuant to 35 U.S.C. § 271(e)(2), by filing ANDA No. 209941 under 21 U.S.C. § 355(j) seeking approval to engage in the commercial manufacture, use and/or sale of such generic sodium sulfate, potassium sulfate, and magnesium sulfate oral solution before the expiration of the ’149 patent.

20. Braintree is entitled under 35 U.S.C. § 271(e)(4) to full relief from Lannett's acts of infringement, including an Order by this Court ensuring that the effective date of any approval from the FDA of ANDA No. 209941, relating to Lannett's proposed generic oral solution, shall not be earlier than the expiration of the exclusivity afforded the '149 patent.

21. This Complaint is being filed before the expiration of the forty-five day period from the day after Braintree received the Lannett Notice Letter. Braintree received the Lannett Notice Letter on February 9, 2017.

COUNT I (INFRINGEMENT OF THE '149 PATENT BY LANNETT)

22. Each of the preceding paragraphs 1 through 21 is incorporated as if fully set forth.

23. Lannett's submission of ANDA No. 209941 to obtain approval to engage in the commercial manufacture, use, and/or sale of such sodium sulfate, potassium sulfate and magnesium sulfate oral solution prior to the expiration of the '149 patent constitutes infringement of one or more of the claims of the '149 patent under 35 U.S.C. § 271(e)(2)(A).

24. Specifically, the composition and the way it is proposed to be made, used and sold as described in Lannett's Notice Letter, will, if marketed and sold, infringe every limitation of at least claims 15, 18, 19, 20, and 23 of the '149 patent. According to Lannett's Notice Letter, and upon information and belief, the components of Lannett's proposed generic product have the same active ingredients, the same route of administration, dosage form, and the same strengths as the corresponding components of SUPREP.

25. Lannett's generic product described in its Notice Letter will practice each and every limitation of at least claim 15, for example. Claim 15 recites:

> A composition for inducing purgation of the colon of a patient, the composition comprising from about 100 ml to about 500 ml of an aqueous hypertonic solution comprising an effective amount of Na_2SO_4, an effective amount of $MgSO_4$, and an effective amount of K_2SO_4, wherein the composition does not produce any clinically significant electrolyte shifts and does not include phosphate.

26. On information and belief, Lannett's proposed generic product described in its Notice Letter is a composition for inducing purgation of the colon of a patient. Lannett's Notice Letter states that Lannett submitted its ANDA "containing information concerning the bioavailability and/or bioequivalence" of the "oral solution that is the subject of Braintree's NDA No. 022372." Lannett's Notice Letter also states that Lannett's ANDA product "will be marketed for the currently approved indications for SUPREP."

27. Lannett's proposed generic product described in its Notice Letter is an aqueous hypertonic solution comprising from about 100 ml to about 500 ml, comprises an effective amount of Na_2SO_4, an effective amount of $MgSO_4$, and an effective amount of K_2SO_4, and does not produce any clinically significant electrolyte shifts. Lannett's Notice Letter states, "the product that is the subject of LANNETT's ANDA No. 209941 ("Lannett's ANDA product") is an oral solution provided as two 6 ounce bottles, each bottle containing magnesium sulfate (1.6 g), potassium sulfate (3.13 g), and sodium sulfate (17.5 g)." Lannett's Notice Letter also states, its "solution is clear and colorless when diluted to a final volume of 16 ounces with water," 16 ounces being equivalent to 473 ml. In addition, Lannett's Notice Letter states, "LANNETT'S ANDA product will be marketed for the currently approved indications for SUPREP." Therefore, Lannett's proposed generic product : 1) will induce purgation of a colon of a patient because it will be administered, upon information and belief, using the same dosing regimen as SUPREP; 2) will be a composition comprising a 100 ml to 500 ml aqueous hypertonic solution because it will be administered as a 473 ml solution and will be a hypertonic solution like SUPREP; 3) will comprise effective amounts of sodium sulfate, magnesium sulfate, and potassium sulfate to induce purgation of a colon, because, upon information and belief, it will be administered using the same dosing regimen as SUPREP; and 4) will not cause clinically

significant electrolyte shifts, because, upon information and belief, it will be administered using the same dosing regimen as SUPREP.

28. The only purported basis for noninfringement of claim 15 in Lannett's Notice Letter is that its proposed generic product contains phosphate.

29. Lannett's proposed generic product does not include phosphate within the meaning of the claims of the '149 patent. Lannett's Notice Letter identifies the active ingredients in its proposed drug product as magnesium sulfate, potassium sulfate, and sodium sulfate. It does not identify phosphate as an active ingredient. Therefore, and upon information and belief, to the extent phosphate is alleged to be in Lannett's proposed generic product, the presence of phosphate does not exclude the proposed generic product from the claimed compositions because any such phosphate is different from the sulfate salts and phosphate recited in at least, for example, claim 15 of the '149 patent. Accordingly, Lannett's proposed generic product contains each and every element of at least, for example, claim 15 of the '149 patent.

30. Upon information and belief, Lannett had actual and constructive knowledge of the '149 patent prior to filing ANDA No. 209941, and was aware that the filing of its ANDA with the FDA constituted an act of infringement of the '149 patent.

31. Upon information and belief, use of such generic sodium sulfate, potassium sulfate and magnesium sulfate oral solution, in accordance with and as directed by the proposed labeling in ANDA No. 209941 for that product, would infringe one or more claims of the '149 patent.

32. Upon information and belief, Lannett knows that its generic sodium sulfate, potassium sulfate and magnesium sulfate oral solution, and the proposed labeling for that product, are especially made or adapted for use in infringing the '149 patent, and that the generic

sodium sulfate, potassium sulfate and magnesium sulfate oral solution and the proposed labeling are not suitable for any substantial noninfringing use. Upon information and belief, Lannett plans and intends to infringe, and will induce and/or contribute to the infringement of, the '149 patent, immediately and imminently upon approval of ANDA No. 209941.

33. Upon FDA approval of Lannett's ANDA No. 209941, Lannett will infringe the '149 patent by making, using, offering to sell, and selling such generic sodium sulfate, potassium sulfate and magnesium sulfate oral solution in the United States and/or importing such solution into the United States, and by actively inducing and contributing to infringement by others, in violation of 35 U.S.C. § 271 (a)-(c), unless enjoined by the Court.

34. If infringement of the '149 patent by Lannett is not enjoined, Braintree will suffer substantial and irreparable harm for which there is no adequate remedy at law.

REQUEST FOR RELIEF

WHEREFORE, Braintree requests that this Court grant the following relief:

1. A judgment that one or more claims of the '149 patent are infringed by Lannett's submission of ANDA No. 209941, and that the making, using, offering to sell, or selling in the United States, or importing into the United States, of the proposed generic sodium sulfate, potassium sulfate and magnesium sulfate oral solution by Lannett will infringe, actively induce infringement, and/or contribute to the infringement of the '149 patent;

2. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of ANDA No. 209941 shall be a date which is not earlier than the expiration date of the '149 patent, including any extensions and/or additional periods of exclusivity to which Braintree is or becomes entitled;

3. An order permanently enjoining Lannett, its affiliates, subsidiaries, and each of its officers, agents, servants and employees, and those acting in privity or concert with it, from

making, using, offering to sell, or selling in the United States, or importing into the United States, such generic sodium sulfate, potassium sulfate and magnesium sulfate oral solution until after the expiration date of the '149 patent, including any extensions and/or additional periods of exclusivity to which Braintree is or becomes entitled;

4. That Braintree be awarded its attorneys' and experts' fees and costs of this litigation; and

5. Such further relief as this Court deems proper and just, including but not limited to any appropriate relief under Title 35.

Dated March 20, 2017.

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